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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/694,777	10/23/00	PARDO-FERNANDEZ	L	MPG-8

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EXAMINER	
WEGERT, S	
ART UNIT	**PAPER NUMBER**
1647	10

DATE MAILED: 08/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/694,777	Applicant(s) PARDO-FERNANDEZ ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 14, 15 and 32, drawn to nucleic acids, compositions comprising nucleic acids, complementary nucleic acids, vectors, host cells, and methods of producing polypeptides recombinantly, classified in class 435, subclass 69.1+.

II. Claim 8, drawn to a multicellular organism transformed with a recombinant vector, classified in class 800, subclass 8+.

III. Claims 11, 15, 32, and 33, drawn to a polypeptide K^+-channel and compositions comprising, classified in class 530, subclass 350+.

IV. Claims 12, 13, 15 and 32, drawn to antibodies against a polypeptide, classified in class 536, subclass 23.5.

V. Claims 16-18, 20, 21, 25, 30 and 31, drawn to a method of gene therapy, classified in class 514, subclass 44.

VI. Claims 19-21 and 30, drawn to a method of modulating the activity of a polypeptide using an antibody, classified in class 536, subclass 23.5.

VII. Claims 19-21, drawn to a method of modulating the activity of a polypeptide using an H_1 antagonist, classified in class 514, subclass 89+.

VIII. Claims 22 and 24, drawn to methods of molecular modeling, classification dependent upon structure of recited compound.

IX. Claims 23 and 24, drawn to a method of identifying inhibitors of nucleic acid expression, classified in class 435, subclass 6.

X. Claims 26-30, drawn to a method of detecting a polypeptide, classification dependent upon structure of recited compound.

XI. Claims 26, 29 and 30, drawn to a method of detecting a polynucleotide, classification dependent upon structure of recited compound.

Furthermore, applicant is required to elect one sequence from one of the following groups.

a) SEQ ID NO: 3 or 4

b) SEQ ID NO: 13 or 14

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-IV are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The nucleic acid of groups I and II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group III can

be used other than to make the antibody of Group IV, such as used as a probe, or used therapeutically.

Groups I and II are related to group III as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Inventions I and II are related to Inventions V, VIII, IX and XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide of Group I can be used therapeutically, as in gene therapy.

Inventions I and II are unrelated to inventions VI, VII, and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide of Group I is neither used in nor produced by any of the methods of Groups VI, VII and IX.

Invention III is unrelated to Inventions V, VI, VII, or IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the

instant case the polypeptide of Group II is neither used in nor produced by any of the methods of Groups IV-V.

Invention III is related to Invention VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group III can be used therapeutically, or used to raise antibodies.

Invention III is related to Invention X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group III can be used therapeutically, or used to raise antibodies.

Invention III is unrelated to invention XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of Group III is neither used in nor produced by the methods of Groups X.

Invention IV is unrelated to inventions V, VII, VIII, IX, and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the antibody of Group IV is neither used in nor produced by the methods of Groups V, VII, VIII and IX.

Invention IV is related to Invention VI and possibly to invention IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody of Group IV can be used for immunoprecipitation of a peptide.

Inventions I, V, VI, VII, VIII, IX, X, and XI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals.

Furthermore, each set of sequences (a) – (b) represents a patentably distinct invention. Groups (a) and (b) are independent and distinct, each from the other, because they have different putative functions, different structures, and require completely different search terms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid of Groups (a) and (b) requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through XI, and must additionally elect from Groups (a) and (b). Applicant is advised that in order for the reply

to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

August 27, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud